



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2010-0524; FRL-9363-4]

RIN 2070-ZA16

#### Trinexapac-ethyl; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of trinexapac-ethyl in or on multiple commodities and modifies existing tolerance levels and commodity definitions for trinexapac-ethyl, which are identified and discussed later in this document. EPA proposed these tolerances and noted amendments under the Federal Food, Drug, and Cosmetic Act (FFDCA) in order to correct inadvertent errors in the final rule tolerance table for trinexapac-ethyl that published in the **Federal Register** on March 2, 2012.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

#### SUPPLEMENTARY INFORMATION).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2010-0524, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), EPA West Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading

Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Bethany Benbow, Registration Division (7505P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 347-8072; email address: [benbow.bethany@epa.gov](mailto:benbow.bethany@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

#### *B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Government Printing Office's e-CFR site at

*[http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).*

### *C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2010-0524 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any CBI) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2010-0524, by one of the following methods:

- *Federal eRulemaking Portal:* <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Background**

In the **Federal Register** of July 13, 2012 (77 FR 41346) (FRL-9353-9), EPA issued a proposed rule pursuant to FFDCA section 408(e), 21 U.S.C. 346a (d)(3). The Agency-initiated rule proposed that 40 CFR 180.662 be amended by establishing tolerances for trinexapac-ethyl in or on barley, bran at 2.5 ppm; sugarcane, molasses at 2.5 ppm; and wheat, bran at 6.0 ppm. The rule also proposed amending the existing trinexapac-ethyl tolerances for wheat, forage from 1.5 to 1.0 ppm and wheat, middlings from 6.5 to 10.5 ppm, as well as changing the existing commodity definition for “hog, kidney” to “hog, meat by-products” in order to correct inadvertent errors in the final rule tolerance table for trinexapac-ethyl that was published in the **Federal Register** on March 2, 2012 (77 FR 12740) (FRL-9337-9). The proposed rule included a summary of the exposure assessment prepared by the Agency and explained the basis for EPA’s conclusion that there is a reasonable certainty that no harm will result to the general population or to infants and children, as a result of aggregate exposure to trinexapac-ethyl residues. A comment was received in response to the proposed rule. EPA’s response to that comment is discussed below in Unit III.

### **III. Response to Comment**

An anonymous citizen objected to the presence of any pesticide residues on food. The Agency understands the commenter's concerns and recognizes that some individuals believe that pesticides should be banned completely. However, the existing legal framework provided by section 408 of the Federal Food, Drug and Cosmetic Act (FFDCA) contemplates that tolerances greater than zero may be set when persons seeking such tolerances or exemptions have demonstrated that the pesticide meets the safety standard imposed by that statute. This citizen's comment appears to be directed at the underlying statute and not EPA's implementation of it; the citizen has made no contention that EPA has acted in violation of the statutory framework.

### **IV. Conclusion**

Given that EPA received no meaningful comment on its proposal and based on the information, analysis, and conclusions in the July 13, 2012 proposal (77 FR 41346) (FRL-9353-9), tolerances are established, as proposed, for residues of trinexapac-ethyl, in or on barley, bran at 2.5 ppm; sugarcane, molasses at 2.5 ppm; and wheat, bran at 6.0 ppm. In addition, as proposed, the tolerance level for wheat, forage is revised from 1.5 to 1.0 ppm, the tolerance level for wheat, middlings is revised from 6.5 to 10.5 ppm and the commodity definition, "hog, kidney" is revised to "hog, meat by-products."

### **V. Statutory and Executive Order Reviews**

This final rule establishes tolerances under FFDCA section 408(d) on EPA's own initiative. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this final rule has been exempted

from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Pursuant to the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), the Agency hereby certifies that these proposed tolerances will not have significant negative economic impact on a substantial number of small entities. Establishing a pesticide tolerance or an exemption from the requirement of a pesticide tolerance is, in effect, the removal of a regulatory restriction on pesticide residues in food, and thus such an action will not have any negative economic impact on any entities, including small entities.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined

that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA) (15 U.S.C. 272 note).

#### **VI. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: September 25, 2012.

**Daniel J. Rosenblatt,**

*Acting Director, Registration Division, Office of Pesticide Programs.*



Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. In § 180.662, the table in paragraph (a) is amended by:

i. Alphabetically adding the following commodities: “Barley, bran”,  
“Sugarcane, molasses”, and “Wheat, bran”.

ii. Removing the entry for “Hog, kidney” and adding in alphabetical order an entry  
for “Hog, meat by-products”.

iii. Revising the entries for “Wheat, forage” and “Wheat, middlings”.

The amendments read as follows:

**§180.662 Trinexapac-ethyl; tolerances for residues.**

(a) \* \* \*

Commodity	Parts per million
Barley, bran	2.5
* * *	* *
Hog, meat by-products	0.03
* * *	* *
Sugarcane, molasses	2.5
Wheat, bran	6.0
Wheat, forage	1.0
* * *	* *

Wheat, middlings	10.5
* * *	* *

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[FR Doc. 2012-24646 Filed 10/04/2012 at 8:45 am; Publication Date: 10/05/2012]